

Declaration Under 37 C.F.R. §1.132

USSN 07/713,624



PATENT APPLICATION

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

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Adang et al

AUG 23 1994

Application No: 07/713,624

Group Art Unit: 1804

BOARD OF PATENT APPEALS
AND INTERFERENCES

Filed: June 10, 1991

Examiner: Dr. Che Chereskin

For: INSECT RESISTANT PLANTS

DECLARATION OF KEITH A. WALKER UNDER 37 C.F.R. §1.132

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

I, Keith A. Walker, declare as follows:

1. I am a citizen of the United States.
2. I reside in San Diego, California.
3. I have extensive experience in the field of cellular biology and knowledge relating to transforming plant cells with insecticidal protoxin genes to express insecticidal proteins and regenerating from such cells transformed plant tissue and plants that express the insecticidal proteins. In carrying out my position as a Senior Research Scientist, I keep up to date on

Declaration Under 37 C.F.R. §1.132**USSN 07/713,624**

the technical literature and maintain contact with experts in the field by participating in professional meetings and by direct personal contacts.

4. My education, employment, publications, and other professional data are listed in my résumé, which is annexed hereto as Attachment 1.

5. I am familiar with the above-identified application and issues pertaining thereto. I am particularly familiar with the laboratory data supporting the disclosures of the identified application relating to plant line AF 103 and the observed 1.7 kbp mRNA fragment.

6. It is my opinion that the practice of science as it might appear to the non-scientist is often characterized by clear, testable hypotheses; unequivocal results and never any evidence contradictory to conclusions. This could not be farther from the truth. Science is most often a messy hodgepodge of observations and data, much of which suggests tendencies and directions - the evolution of "working hypotheses". Finally, enough information is gained that an insight is achieved which only then allows for an unambiguous evaluation of a clearly stated testable hypothesis. Often scientists of good reputation subsequently reach alternative interpretations of their experimental data. These differing interpretations are often based on changes in technology or subsequent test results.

7. On page 125 of the specification, Applicants disclose the following:

Declaration Under 37 C.F.R. §1.132**USSN 07/713,624**

Northern blot analysis of RNA generally demonstrated the presence of mRNA having crystal protein sequences. These mRNA molecules were not the expected size of about 3.8 kbp, but were about 1.7 kbp in size. This was sufficient to encode the toxic portion [o]f the crystal protein.

8. Review of the initial northern blot data during Interference No. 103,324 has revealed that the 1.7 kbp fragment is an artifact. Also, a review of the molecular weight standards used in the experiments indicates that the mRNA fragment is probably only about 1Kb in length, not 1.7 Kb due to the inadvertent error of E. Murray, an Agrigenetics scientist. Therefore, it appears that the "1.7"Kb band is an artifact of the screening procedure used to detect mRNA and not an insecticidal portion of the *B.t.* crystal protein.

9. On page 124 of the specification, Applicants disclose the following:

Clone 103 also gave high mortality explained by the subsequently discovered fact that "clone" 103 was not in fact a clone; the original transformed plant has now been shown to have been a chimeric plant. It [plant 103] has not proven to be particularly insecticidal in any other of the five trials.

The conclusion that AF 103 was in fact a chimeric plant appears to have been based on the northern blot analysis which detected the presence of

Declaration Under 37 C.F.R. §1.132**USSN 07/713,624**

a 1.7 kbp mRNA fragment. However, subsequent test data suggests that this conclusion is incorrect.

10. Subsequent ELISA and insect bioassay analyses indicate that AF 103 was negative for the *B.t.* gene. The only 'positive' result was in the northern blot containing the 1.7 Kb band, which was interpreted to be a break-down product of the full-length *B.t.* gene. The northern blot data was initially interpreted as showing that AF 103 was a chimeric plant. However, in view of other test data including Southern analysis, ELISA and bioassays, it appears that the northern blot data was inadvertently misinterpreted.

11. It is my expert opinion that Applicants' initial misinterpretation of northern blots and of the data on AF 103 would not affect the ability of one of ordinary skill in the art to practice the invention as claimed because the data is not the sole indicator of whether *B.t.* toxin protein is being expressed. Other assays such as DNA analysis, ELISAs, SDS-PAGE, and bioassays were available to determine whether a particular clone expressed a gene of interest. In fact, it is the data obtained from these other techniques that permits proper reconsideration of the northern blot analysis.

12. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable

Declaration Under 37 C.F.R. §1.132

USSN 07/713,624

by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Date: August 21, 1994

Keith A. Walker Keith A. Walker